



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,850	03/29/2001	Michael P. Bevilacqua	2331/112US	3553

2101 7590 08/21/2002
BROMBERG & SUNSTEIN LLP
125 SUMMER STREET
BOSTON, MA 02110-1618

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 08/21/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,850

Applicant(s)

BEVILACQUA ET AL.

Examiner

Marianne P. Allen

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35, 43-155 and 167-174 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-35, 43-155 and 167-174 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 4-8, 16-17, 20-25, 28-35, 43-45, 53-56, 58-59, and 69-71, drawn to a method for evaluating a biological condition in a subject, classified in class 435, subclass 6.
- II. Claims 2, 4-8, 16-17, 20-25, 28-35, 43-45, 53-56, 58-59, and 69-71, drawn to another method of evaluating a biological condition in a subject, classified in class 435, subclass 7.1.
- III. Claims 3, 8, 10-15, 18-23, 26-35, 43-44, 46-65, and 69-71, drawn to a method for evaluating the effect on a biological condition, classified in class 435, subclass 6.
- IV. Claims 66-68, drawn to another method for evaluating the effect on a biological condition, classified in class 435, subclass 7.1.
- V. Claims 72-76, drawn to a method of conducting a clinical trial, classified in class 702, subclass 19.
- VI. Claims 77-87, drawn to a digital storage medium, classified in class 360, subclass 135.
- VII. Claims 88-89, drawn to another digital storage medium, classified in class 360, subclass 135.
- VIII. Claim 90, drawn to another digital storage medium, classified in class 360, subclass 135.

- IX. Claims 91-97 and 100-101, drawn to another method for evaluating a biological condition in a subject, classified in class 435, subclass 6.
- X. Claims 98-99, drawn to a method of displaying quantitative gene expression analysis data, classified in class 702, subclass 19.
- XI. Claims 102-106, drawn to a descriptive record, classified in class 360, subclass 135.
- XII. Claim 107, drawn to a method of diagnosis, classified in class 702, subclass 19.
- XIII. Claims 108-110, drawn to conducting a clinical trial, classified in class 702, subclass 19.
- XIV. Claim 111, drawn to a method of diagnosing susceptibility, classified in class 435, subclass 6.
- XV. Claim 112, drawn to a method for monitoring progress, classified in class 435, subclass 6.
- XVI. Claims 113-122 and 124-127, drawn to a method for establishing a descriptive record, classified in class 702, subclass 19.
- XVII. Claim 123, drawn to selecting a therapeutic agent, classified in class 702, subclass 19.
- XVIII. Claim 128, drawn to method for characterizing effectiveness, classified in class 702, subclass 19.
- XIX. Claims 129-136, drawn to a method for accessing biological information, classified in class 702, subclass 19.

- XX. Claims 137-138, drawn to a method for consumer evaluation of a product, classified in class 702, subclass 19.
- XXI. Claims 139-140, drawn to a computer program product and computer system, classified in class 707, subclass 100.
- XXII. Claim 141, drawn to a method for analyzing a patient, classified in class 702, subclass 19.
- XXIII. Claims 142-143, drawn to a method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXIV. Claims 144-145, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXV. Claims 146-147, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXVI. Claims 148-149, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXVII. Claims 150-151, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXVIII. Claims 152-153, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXIX. Claims 154-155, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.
- XXX. Claims 164-166, drawn to a kit, classified in class 536, subclass 24.3.

XXXI. Claims 167-174, drawn to another method for evaluating a biological condition of a subject, classified in class 435, subclass 7.1.

Applicant is advised that if Group I, II, or III is elected, the indicated claims will be examined only to the degree that they reflect the method of the independent claim (claim 1, 2, or 3). It is noted that many of the claims are multiply dependent and appear in more than one group. Applicant is advised that if either Group XII or XIII is elected, applicant must further elect the particular method upon which claims 107 and 108 depend (claim 1, 2, or 3) for examination. These claims are directed to three distinct methods of diagnosis and three distinct methods of conducting a clinical trial in view of the multiple dependency of claim 107.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-V, IX-X, XII-XX, XXII-XXIX, and XXXI can be shown to be distinct, each from any other, because they each have different starting materials, method steps, and/or goals. The products of Groups VI-VIII, XI, XXI, and XXX can be shown to be distinct, each from any other, because they differ structurally and functionally. Note that each of the digital storage media are required to store different information. Each of the products can be shown to be distinct from each of the methods as the product is either not used by the method or can be used in multiple methods.

Because these inventions are distinct for the reasons given above and the non-patent literature search required for each group is not coextensive with that required for any other group, restriction for examination purposes as indicated is proper.

Art Unit: 1631


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
August 15, 2002